

Pertussis Vaccines Working Group Update

Mark Sawyer, MD

Chair, ACIP Pertussis Vaccine Work Group

Advisory Committee for Immunization Practices

June 19, 2013

Work Group Members

(formation in April 2009)

ACIP Members

Mark Sawyer, Chair
Kathleen Harriman

Ruth Karron
Marietta Vázquez

Ex Officio Members

Xin-Xing Gu (NIAID)

Ann Schwartz (FDA)

Liaison Representatives

Richard Beigi (ACOG)
Albert Bourbon (AAPA)
Alexis Elward (HICPAC)
Stanley Gall (ACOG)

Christine Hahn (CSTE)
Jessica Kahn (SAM)
Harry Keyserling (SHEA)
Tom Koinis (AAFP)

Sarah Long (AAP)
Stephanie Schauer (AIM)
Kenneth Schmader (AGS)
Matthew Zahn (NACCHO)

Invited Consultants

William Atkinson
Carol Baker
Lance Chilton

Kris Ehresmann
Scott Halperin (Canada)
Peter McIntyre (Australia)

Bruce Meade
Paul Offit

CDC Designated Federal Officer

Jennifer Liang

Terms of Reference

- ❑ Review existing statements on infants and young children (1997), adolescent (2006), adults (2006), and pregnant and postpartum women and their infants (2008) and consolidate into a single statement.
- ❑ Review new data on Tdap including
 - Effectiveness of ACIP recommendations
 - Interval between Td booster and Tdap
 - Use of Tdap in adults ages 65 yrs and older
 - Pregnant and breastfeeding women
 - Use of Tdap
 - Cocooning strategies
 - Vaccinated HCP and need for postexposure prophylaxis
 - Tdap revaccination
 - Pregnant women
- ❑ Review updated epidemiology of tetanus and diphtheria

Tdap Vaccines: Licensure and Composition

Trade name, Manufacturer	Age approved for use (yrs)	Antigen (µg)				Toxoid (Lf)	
		PT	FHA	PRN	FIM 2 & 3	Diphtheria	Tetanus
Adacel Sanofi Pasteur	11 - 64	2.5	5	3	5	2	5
Boostrix GSK	10 and older	8	8	2.5	-	2.5	5

*PT - pertussis toxin; FHA - filamentous haemagglutinin; PRN - pertactin; FIM - fimbriae

Current ACIP Recommendations for Tdap

❑ A single Tdap dose

- Adolescents aged 11 through 18 years, preferred 11 or 12 years
- Adults aged 19 years and older
- Further guidance will be forthcoming on timing of revaccination in persons who have received Tdap previously
- Pregnant women are recommended Tdap with every pregnancy

❑ Decennial Td booster for those who have received 1 Tdap

- 5 years for wound management

CDC's Immunization Safety Office: Summary of Monitoring Activities for Maternal Tdap Safety

- ❑ Vaccine Adverse Event Reporting System (VAERS)**
 - Ongoing monitoring

- ❑ Vaccine Safety Datalink (VSD)**
 - Available coverage data
 - Safety studies have been initiated

- ❑ Clinical Immunization Safety Assessment (CISA) Project**
 - Potential for targeted prospective clinical studies

Adapted from the "Update on immunization safety monitoring: Tdap administered to pregnant women". Presented to the Advisory Committee on Immunization Practices (ACIP), Atlanta, GA; February 20, 2013.

Preliminary Tdap Coverage in Pregnancy Vaccine Safety Datalink, 2007-2011

- **All years combined and all participating VSD sites: few women received Tdap during pregnancy**
 - 6.1% of all pregnancies
 - 7.2% of pregnancies ending in a live birth
- In 2011, VSD sites** except California
 - Tdap coverage during pregnancy was 1.6% *
- In 2011, California
 - Tdap coverage during pregnancy was 29.3% *
- **Data to date do not reflect updated ACIP recommendations**
 - Current data is through Nov 2011
 - 2012 data anticipated availability in Fall 2013 and may begin to reflect ACIP recommendations (based on California data)

*pregnancies ending in live birth; ** MN, WI, CO, OR and WA VSD sites

Why Addressing Tdap Revaccination?

- ❑ Increasing burden of pertussis in United States**
- ❑ Tdap recommended since 2005**
 - After one Tdap, ACIP recommends Td every 10 years or 5 years for wound contamination.
 - Almost 10 years since one dose of Tdap recommended
- ❑ Data available on Tdap vaccine effectiveness and second dose Tdap safety and immunogenicity**

ACIP Pertussis Vaccines Session February 2013

- ❑ **Pertussis in the United States and Tdap revaccination**
 - Resurgence of pertussis expected to continue
 - Evidence of direct protection from adolescent Tdap, no herd immunity
 - Tdap effectiveness and waning of protection will likely influence the impact of revaccination strategies

- ❑ **ACIP guided WG to consider a second Tdap dose, not multiple doses**

Today's Session

- ❑ **Pertussis in the US and Tdap vaccine effectiveness** **Dr. Anna Acosta**
- ❑ **Tdap revaccination: antibody persistence, safety and immunogenicity** **Dr. Jennifer Liang**
- ❑ **Decision and cost effectiveness analysis: a second Tdap dose** **Dr. Hajime Kamiya**
- ❑ **WG conclusions on a second Tdap dose (No vote)** **Dr. Jennifer Liang**
- ❑ **Discussion**
- ❑ **Maternal Tdap effectiveness:**
 - Australia
 - United Kingdom**Dr. Peter McIntyre**
Dr. David Salisbury
- ❑ **Discussion**

Revaccination Scenarios

**Current
recommended
schedule**



**Scenario #1
2nd adolescent
Tdap**



**Scenario #2
Replace 1st Td
with Tdap**

